

The 35 U.S.C. § 102(e) Rejection

Claims 1-2 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Burney, et al.<sup>1</sup> This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.<sup>2</sup> “In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.”<sup>3</sup> Moreover, the M.P.E.P further states that “the particular part of the reference relied upon to support the rejection should be identified” by the Examiner.<sup>4</sup> “There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.”<sup>5</sup>

Claim 1 is an independent claim with claim 2 depending from claim 1.

A. The Office Action specifically states:

“In figures 1-10, Burney et al. (5800389) disclose a system having a catheter 15 including a closed distal end 30 and a side port 24 adjacent to the distal end, and adaptor or hub 40 having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the adaptor

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<sup>1</sup> USP 5,800,389.

<sup>2</sup> Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

<sup>3</sup> *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984).

<sup>4</sup> Manual of Patent Examining Procedure (MPEP) § 706.02(i).

<sup>5</sup> *Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

is removable, as recited in claim 1. The examiner notes that the adaptor and the catheter/cannula are structurally equivalent to the claimed subject matter.”<sup>6</sup>

Claim 1 provides for the following limitations:

“a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue; and

an adaptor connected to the catheter for hydrating and delivering the pledget to the catheter”

As stated in the Specification and as claimed in claim 1, the catheter is “for delivering a pledget of sponge material in a hydrated state to the tissue”. (See, Specification, page 16, paragraph 63). Moreover, as stated in the Specification and as claimed in claim 1, the adaptor is “for hydrating and delivering the pledget to the catheter.” (See Specification page 7, paragraph 40; page 8, paragraph 41).

“The particular part of the reference relied upon to support the rejection should be identified” by the Examiner.<sup>7</sup> However, the Examiner merely recites parts of the invention disclosed in Burney and “notes that the adaptor and the catheter/cannula are structurally equivalent to the claimed subject matter” without any other explanation. As further discussed below, it is unclear why the Examiner would note that the adaptor and the catheter/cannula are structurally equivalent to the claimed subject matter. It is respectfully requested that the Examiner provide the particular parts of the reference

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<sup>6</sup> Office Action ¶ II.

<sup>7</sup> Manual of Patent Examining Procedure (MPEP) § 706.02(i).

which is used to “note that the adaptor and the catheter/cannula are structurally equivalent to the claimed subject matter” to clarify the rejection so that Applicant may provide a proper response. In any event, Applicant has attempted to provide a proper response to the Office Action.

Burney merely teaches a biopsy devices “which provide safe and efficient coaxial, cofocal and eccentric sampling with only a single biopsy device placement.” (Col. 1, lines 7-9). Burney “provides biopsy devices and methods for obtaining biopsies . . . [for] precise tissue sampling and improved safety features. This invention compensates for sampling errors and accommodates the need for obtaining multiple samples without multiple device placements.” (Col. 4, lines 41-47). Burney teaches “an introducer 15 which . . . includes a cannula 20.” (Col. 4, lines 60-61). “The cannula 20 also defines a lateral opening 24 . . . sized and configured to allow exit of a biopsy needle from the cannula as it is advanced through the lumen 25. The lateral opening 24 allows the practitioner to sample multiple areas.” (Col. 5, lines 4-9). No where does Burney teach the cannula “delivering a pledget of sponge material in a hydrated state to the tissue” as claimed in claim 1. Applicant respectfully requests that the Examiner cite the particular part of the reference relied upon to support this rejection.

The Office Action equates the hub 40 of Burney to the adaptor of the claimed invention. Applicant respectfully disagrees with this analogy. The hub as disclosed in Burney is merely “for delivering a biopsy needle to the cannula.” (Col. 6, line 15). No

where does Burney teach or suggest a hub “for hydrating and delivering the pledget to the catheter” as claimed in claim 1. In fact, the hub as taught in Burney would not be able to hydrate and deliver a pledget to the catheter. Applicant respectfully requests that the Examiner cite the particular part of the reference relied upon to support this rejection.

B. The Office Action also specifically states:

“In addition, they are two separate pieces, hence the adaptor is removable from the catheter/cannula. See also columns 6 and 9.”<sup>8</sup>

Claim 1 provides for the following limitation “wherein the adapter is removable from the catheter.” The Specification provides that the “luer fitting 36 of the adaptor 12 is connected to the biopsy needle hub.” (Specification, page 12, paragraph 49).

Upon a closer reading of Burney and of the cites provided by the Examiner, Burney does not teach an adapter that is removable from the catheter. The Examiner cites columns 6 and 9. However, columns 6 and 9 merely teach the following:

“the invention includes a hub 40 attached to the second end 22 of the cannula” (Col. 6, lines 12-13).

and

“the hub is engaged to the cannula by conventional techniques such as insert molding.” (Col. 9, lines 42-43).

No where does Burney teach the hub being “removable from the catheter” as claimed in claim 1. Rather Burney teaches the hub as being attached to the cannula by insert

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<sup>8</sup> Office Action ¶ II.

molding techniques which implies that the hub is not detachable from the cannula.

Again, Applicant respectfully requests that the Examiner cite the particular part of the reference relied upon to support this rejection. In fact, it would not have been obvious to one of ordinary skill in the art to make the hub of Burney removable from the cannula because the hub is used for holding the cannula and manipulating the cannula to a biopsy site. Thus, the hub needs to be fixed to the cannula to perform this function. This is further supported in Burney which states that the “hub 40 preferably includes a gripping portion 41 . . . configured to be held by the practitioner during insertion and positioning of the introducer 19.” (Col. 6, lines 32-35). Having a removable hub would be contrary to the teaching of Burney which provides for the “extremely precise tissue sampling . . . [and] compensates for sampling errors.” (Col. 4, lines 44-45).

Thus, since each and every element as set forth in claim 1 is not found, either expressly or inherently described in Burney, it can not be said to anticipate the claimed invention.

The 35 U.S.C. § 103 Rejection

Claims 7-9 and 24 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Burney in view of Burbank,<sup>9</sup> and further in view of Riley et al.<sup>10</sup> among which claims 7 and 24 are independent claims. This rejection is respectfully traversed.

According to the Manual of Patent Examining Procedure (M.P.E.P.),

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.<sup>11</sup>

Specifically, the Office Action states:

“The combination teaching of Burney et al. ‘389 in view of Burbank et al. (5775333) show a system for sampling tissues. However, the combination teaching of Burney et al. ‘389 in view of Burbank et al. (5775333) fails to disclose a pledget of sponge material, wherein the sponge material is radiopaque marker.

Nonetheless, Riley et al. teach a device for delivering a bioabsorbable Gelfoam or pledget, wherein the pledget is a radiopaque marker or media to a biopsy site.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify the combined teaching of Burney et al. ‘389 in view of Burbank et al. (5775333) with a radiopaque marker made of a sponge material, as taught by Riley et al.”<sup>12</sup>

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<sup>9</sup> USP 5,775,333.

<sup>10</sup> “Percutaneous Liver Biopsy . . . “

<sup>11</sup> M.P.E.P § 2143.

<sup>12</sup> Office Action ¶ V.

The Applicants respectfully disagree for the reasons set forth below.

Claim 7 provides for the following limitations:

“A system for injecting a sponge into tissue, the system comprising:

a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue;

an adaptor connected to the catheter for hydrating and delivering the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter; and

a pledget of sponge material preloaded in the adaptor.”

Claim 24 provides for the following limitations:

“A system for injecting a sponge into tissue, the system comprising:

a catheter having a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue;

an adaptor connected to the catheter for hydrating and delivering the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter; and

a pledget of radiopaque sponge material loaded in the adaptor.”

A. There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings.

“The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. . . . It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the

claimed invention is rendered obvious.”<sup>13</sup> Thus, an invention is not rendered obvious where the Examiner fails to provide the suggestion in the prior art references.

The combination of the prior art references do not provide any suggestion or motivation to modify or combine the reference teachings to result in the claimed invention. In fact, this is further supported in the office action that specifically states “[t]he combination teaching of Burney et al. ‘389 in view of Burbank et al. (5775333) show a system for sampling tissues.” Thus, the teachings of Burney and Burbank teach biopsy devices which remove or samples tissue, which creates bleeding, rather than stops bleeding. The combined references do not teach a “system for injecting a sponge into tissue” as claimed in claims 7 and 24 to control or stop bleeding. The prior art references can not be pieced together to result in the claimed invention unless the prior art suggested the desirability of the modification. No where do the teachings of Burney or Burbank suggest a system for injecting a sponge into tissue to control or stop bleeding.

Thus, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine reference teachings to result in the claimed invention.

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<sup>13</sup> *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992).

B. The prior art references do not teach or suggest all the claim limitations.

As stated above, the prior art references, either in Burney or Burbank, do not teach or disclose a “catheter . . . for delivering a pledget of sponge material in a hydrated state to the tissue; an adaptor . . . for hydrating and delivering the pledget to the catheter; [or] a pledget of sponge material preloaded in the adaptor” as claimed in the present invention. Applicant respectfully requests that the Examiner cite the particular part of the references relied upon to support this rejection. Thus, the prior art references do not teach or suggest all the claim limitations.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

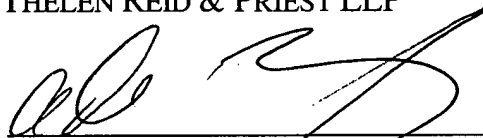
In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,  
THELEN REID & PRIEST LLP



Adrienne Yeung  
Reg. No. 44,000

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THELEN REID & PRIEST LLP  
P.O. Box 640640  
San Jose, CA 95164-0640  
(408) 292-5800 direct dial  
(408) 287-8040 direct fax

**Version with Markings to Show Changes Made****In the Specification:**

Paragraph 0063 was amended as follows:

-- [0063] FIG. 10 illustrates the biopsy cannula 72 and a delivery catheter 90 configured to deliver one or more absorbable sponge pledgets through the cannula to the biopsy site. The delivery catheter 90 includes a closed distal end 92, a side port 94, a tapered section 96, and an enlarged proximal portion 98 for receiving the pledget. The side port 94 of the delivery catheter 90 is arranged to [delivery] deliver the pledget through the side port 74 of the cannula 72. Accordingly, the catheter side port 94 is preferably the same size or smaller than the side port 74 of the cannula 72. The delivery catheter 90 also includes a proximal fitting 100 for connection to a syringe and an indexing element 102. The indexing element 102 engages with the indexing wheel 82 on the cannula 72 to align the side ports 74, 94 of the cannula and catheter. Alternatively, alignment may be performed by aligning a marker on the catheter 90 with a corresponding marker on the cannula, 72. Another system for alignment of the cannula 72 and the delivery catheter may include one or more detents and corresponding recesses or grooves in the shafts of the cannula and catheter. In the alternative, the outer surface of the catheter 90 could be configured to engage the inner surface of the cannula 72 to resist relative movement or displacement between the catheter 90 and the cannula 72. --

In the Claims:

Claims 7 and 24 were amended as follows:

7. (Once Amended) A system for injecting a sponge into tissue, the system comprising:

a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue;

an adaptor connected to the catheter for hydrating and delivering the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter; and

a pledget of sponge material preloaded in the [adapter] adaptor.

24. (Once Amended) A system for injecting a sponge into tissue, the system comprising:

a catheter having a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue;

an adaptor connected to the catheter for hydrating and delivering the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter; and

a pledget of radiopaque sponge material loaded in the [adapter] adaptor.